DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 17, 2014

Pioneer Surgical Technology, Incorporated (*dba* RTI Surgical, Incorporated)
Ms. Sarah McIntyre
Regulatory Affairs Associate II
375 River Park Circle
Marquette, Michigan 49855

Re: K141600
Trade/Device Name: NanOss™, NanOss™ Loaded, NanOss™ Loaded Kit
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: September 16, 2014
Received: September 18, 2014

Dear Ms. McIntyre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141600

Device Name
NanOss™, NanOss™ Loaded, NanOss™ Loaded Kit

Indications for Use *(Describe)*
NanOss™ is intended for bony voids or gaps that are not intrinsic to the stability of bony structure. The product is indicated to be gently packed into bony voids or gaps in the skeletal system (i.e., extremities, posterolateral spine, and pelvis). NanOss must be mixed with autogenous blood or sterile saline for use in the extremities or pelvis. NanOss must be mixed with bone marrow aspirate and autograft bone as a bone graft extender in the posterolateral spine. These defects may be surgically created osseous defects or defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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NanOss™ Bone Void Filler
510(k) Summary Pursuant to 21 CFR 807.92

Sponsor:	Pioneer Surgical Technology, Inc. (DBA RTI Surgical, Inc.) 375 River Park Circle Marquette, MI 49855 USA Contact: Sarah McIntyre Ph: (906) 225-5861 Fx: (906) 226-4459
	Prepared: September 16, 2014
Name:	NanOss™ Bone Void Filler
Common Name:	Bone Void Filler
Trade/Proprietary	NanOss™, NanOss™ Loaded, NanOss™ Loaded Kit
Classification Regulations:	Filler, Bone Void, Calcium Compound (Product Code MQV) 21 CFR 888.3045, Class II
Classification Panel:	Orthopaedic and Rehabilitation Devices
Predicate:	FortrOss Bone Void Filler (K110561) NanOss™ BVF-E (K100361)
Intended Use:	NanOss™ is intended for bony voids or gaps that are not intrinsic to the stability of bony structure. The product is indicated to be gently packed into bony voids or gaps in the skeletal system (i.e., extremities, posterolateral spine, and pelvis). NanOss must be mixed with autogenous blood or sterile saline for use in the extremities or pelvis. NanOss must be mixed with bone marrow aspirate and autograft bone as a bone graft extender in the posterolateral spine . These defects may be surgically created osseous defects or defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.
Description:	NanOss™ is a resorbable bone void filler (BVF) consisting of calcium phosphate and a porcine gelatin carrier provided in granular form. The BVF is radiopaque, provided sterile and is intended for single use only. The product is provided pre-filled in a mixing container as NanOss™ or in a mixing chamber/syringe as NanOss™ Loaded.

The purpose of this submission is to obtain clearance for a merged indications for use statement and new packaging configuration (NanOss™ Loaded Kit). In addition, instrument accessories previously cleared for MIS graft placement in the posterolateral spine through a small incision are now available for graft placement in the skeletal system (i.e., extremities, pelvis).

Testing: The following non-clinical tests were performed to support a determination of substantial equivalence:

- Packaging and Shelf-Life Validations per ASTM D4169-09: DC 13 & 17 and ASTM F1980
- Sterilization Validation per ISO 11137-1
- Instrument Validation Testing

Substantial Equivalence: The bone void filler has the following similarities to the previously cleared bone void filler product (K110561/K100361):

- has the same intended uses,
- uses the same operating principles,
- incorporates the same basic design,
- incorporates the same materials,
- is provided sterile and for single-use.

Conclusion: The comparisons and testing conducted demonstrate the subject bone void filler product described in this submission is substantially equivalent to the predicate devices.